MAY 22 2009

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

## 1. GENERAL INFORMATION

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|---|---|
| Submitter | ANTHOGYR (Registration number 8020776)<br>164 rue des trois lacs<br>74700 SALLANCHES FRANCE<br>Phone: 33(0)4 50 58 02 37 Fax: 33(0)4 50 93 78 60<br>Web : www.anthogyr.com |
| Contacts | Sabine BRAYETTE (QUALITY ENGINEER IN CHARGE OF REGULATORY AFFAIRS) sabine.brayette.prod@anthogyr.com |
| Trade Names | 1 - Anthogyr Contra angles « MontBlanc »<br>2 - Anthogyr Implantology Contra-angles "MontBlanc" |
| Legally marketed predicate devices | 1. Anthogyr Contra angles « MontBlanc » K060317<br>2. Anthogyr Implantology Contra-angles "MontBlanc" Control K070084 |
| Classification Name | Dental handpiece and accessories |
| Class | I |
| Product Code | EFA |
| CFR section | 872.4200 |
| Intended Use | ANTHOGYR's fully autoclavable contra-angles Implantology "MontBlanc" are devices intended for a wide range of dental procedures including:<br>✓ Implant surgery such as perforating the bone, tapping and threading procedures<br>ANTHOGYR's fully autoclavable contra-angles "MontBlanc" are devices intended for a wide range of dental procedures including:<br>✓ General dentistry such as removing carious material, cavity and crown preparation, finishing tooth preparations, restaurations and polishing teeth. |

## 2. INTENDED USE

ANTHOGYR's fully autoclavable contra-angles Implantology "MontBlanc" are devices intended for a wide range of dental procedures including:

- ✓ Implant surgery such as perforating the bone, tapping and threading procedures. This range can be used with special accessories like depth stop.

ANTHOGYR's fully autoclavable contra-angles "MontBlanc" are devices intended for a wide range of dental procedures including:

- ✓ General dentistry such as removing carious material, cavity and crown preparation, finishing tooth preparations, restaurations and polishing teeth.

## 3. DEVICE DESCRIPTION

ANTHOGYR has developed a full range of surgical contra angle intended to be used in implantology. The name of the range is "MontBlanc". ANTHOGYR Contra angles design, size and performance conform to NF EN ISO 7785-2 "Dental Handpieces – Part 2: Straight and geared angle handpieces".

ANTHOGYR has developed a full range of general dentistry contra angle intended to be used in general dentistry. The name of the range is "MontBlanc". ANTHOGYR Contra angles design, size and performance conform to NF EN ISO 7785-2 "Dental Handpieces – Part 2: Straight and geared angle handpieces".

## 4. PERFORMANCE DATA

ANTHOGYR Contra angles & Handpieces conform to the following FDA recognized Consensus standards:

- ✓ ISO 14971 (2007) Medical devices - Application of risk management to medical devices (Recognition List Number: 018 Effective Date: 09/12/2007)
- ✓ ISO 15223 (2007) Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (Recognition List Number: 017 Effective Date: 05/21/2007)
- ✓ ISO 13402 (2007) Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure.(Recognition List Number: 017 Effective Date: 05/21/2007)

- ✓ ISO 7785-2 (2008) Dental handpieces -- Part 2: Straight and geared angle handpieces (Recognition List Number: 020 Effective Date: 07/31/2008)
- ✓ ISO 3964 (1982) DENTAL HANDPIECES - COUPLING DIMENSIONS (Recognition List Number: 003 Effective Date: 05/03/1999)
- ✓ ISO 5832-1 (2008) IMPLANTS FOR SURGERY -- METALLIC MATERIALS -- PART 1: WROUGHT STAINLESS STEEL (Recognition List Number: 020 Effective Date: 07/31/2008)

In addition, ANTHOGYR Contra angles & Handpieces conform to the following standards:

- ✓ ISO 13485 (2004) "Medical devices - Particular requirements for the application of the ISO 9001"
- ✓ NF EN ISO 1797-1 (1995) "Dental rotatory instruments - Shanks - Par 1: Shanks made of metal"
- ✓ NF EN ISO 17664 (2004) « Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices »
- ✓ NF EN ISO 17665-1 (2006) « Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices »

## 5. SUBSTANTIAL EQUIVALENCE

The Implantology Contra-angles "Mont Blanc" have the same fundamental scientific technology, operating principle and intended use as predicate devices.

The Contra-angles "Mont Blanc" have the same fundamental scientific technology, operating principle and intended use as predicate devices.

Summary preparation date: February 19, 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Sabine Brayette
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MAY 22 2009

Re: K090676
Trade/Device Name: Anthogyr Contra Angles and Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: April 24, 2009
Received: April 29, 2009

Dear Sabine Brayette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

anthogyr

## Indications for Use

510(k) Number (if known): K090676

Device Name: ANTHOGYR CONTRA ANGLES AND HANDPIECES

- ✓ **Indications for Use:** ANTHOGYR's fully autoclavable contra-angles Implantology "MontBlanc" and ANTHOGYR's fully autoclavable contra-angles "MontBlanc" are devices intended for a wide range of dental procedures including:
- ✓ Implant surgery such as perforating the bone, tapping and threading procedures
- ✓ General dentistry such as removing carious material, cavity and crown preparation, finishing tooth preparations, restaurations and polishing teeth.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Kevin Mulley for M S P

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090676